

# **EXHIBIT DX1**

**TO DECLARATION OF  
DEBORAH E. LEWIS IN SUPPORT  
OF DEFENDANTS' MEMORANDUM IN  
OPPOSITION TO PLAINTIFFS' MOTION  
TO EXCLUDE TESTIMONY OF  
ANTONIA HUGHES, RN, BSN, MA, CNOR**

June 1, 2017

Ms. Deborah E. Lewis  
Blackwell Burke PA  
431 South Seventh Street, Suite 2500  
Minneapolis, MN 55415

Re: In re: Bair Hugger Forced Air Warming Products Liability Litigation

Dear Ms. Lewis,

At your request, I have reviewed or had available the Master Long Form Complaint and Jury Demand, Defendants' Master Answer to Plaintiffs' Master Long Form Complaint and Jury Demand, Memorandum In Support of Defendants' Proposed Phase I Scheduling Order, and the expert report of Michael J. Stonnington, M.D., all produced in this lawsuit. I have prepared this expert report which expresses my opinions concerning the surgical operating room environment, and in particular the operating room environment during an orthopedic and/or arthroplasty procedure. My expert opinions are based on a reasonable degree of nursing and scientific probability.

### **Educational Background and Experience**

I am a Certified Registered Nurse practicing in the operating room arena. I graduated with a diploma in nursing from Nebraska Methodist Hospital School of Nursing, Omaha NE in 1974. I obtained my BSN from the College of Notre Dame of Maryland, Baltimore, MD in 1995. I received my MA in management from the College of Notre Dame of Maryland, Baltimore, MD in 2000. In 1983, I obtained certification as an operating room nurse (CNOR) and have maintained my certification since that time. I am currently licensed as a Registered Nurse in Maryland, New Jersey, and Massachusetts.

My clinical experience in the operating room spans over thirty-five years in a wide variety of roles and settings. I have practiced proficiently in the scrub nurse role, RN circulator, educator, manager, and director. During my career in the role of the scrub nurse, I have assisted the surgeon in numerous total joint procedures. In that role, I was the team member close to the surgeon monitoring the sterile field and handing the instruments necessary for each step to the surgeon. It is imperative that the scrub nurse be proficient to quickly assist the surgeon during the procedure. In the role of the RN circulator, I have practiced as a team member for total joint procedures, including managing the operating room and the entire surgical team during the surgery.

My career has included leadership roles in the perioperative setting. My role as educator has included development of the curriculum for new operating room nurses. After completion of the course, the nurse could practice as a safe and competent nurse in the perioperative setting.

While serving as a manager and director in the operating room, my responsibilities included involvement in multimillion capitol and expense budgets. One of the components of a good budget includes assurance of the correct type and number of staff for each surgical procedure.

I am an active member of AORN, have served as Chair and member of the Nursing Practice Committee, Chair of the Recommended Practices Advisory Board, Chair and member of the Legislative Committee, and Chair and member of the Transition into Practice Committee. I have published on the implementation of AORN recommended practices for a safe environment of care, and have conducted courses on this topic. I served on the AORN committee involved in the Standards of Perioperative Nursing, 2015 Guidelines for Perioperative Practice, and have presented on AORN Guidelines.

My most recent experience is that of a perioperative education consultant.

See my curriculum vitae for additional experience, publications and presentations, attached as Exhibit A.

### **Introduction to the Operating Room Environment**

The operating room environment is one of rigid rules and regulations put into place to protect the surgical patient and the healthcare worker. The operating room is considered a clean environment with a specific dress code and strict traffic patterns. The traffic patterns relate to unrestricted to restricted areas. The unrestricted areas are the locker rooms where the staff change from their street clothes to surgical scrubs. The rooms/areas where the surgical procedure will be performed are the most restrictive in attire and movement. There are specific temperature/humidity requirements and air handling exchanges. The air handling requirement for an operating room is a minimum of 20 exchanges an hour, with a minimum of 4 air changes of outdoor air. The pressure is maintained<sup>1</sup> as positive pressure to the surrounding rooms. The air flow is unidirectional from the ceiling over and surrounding the operating room bed. It forms a rectangular shape like that of the operating room bed. The air is filtered and the unidirectional downward air flow is strong. While standing next to the operating room bed, the air flow is constantly felt by the staff caring for the surgical patient. The direction of the air flow is from the ceiling down to the operating room bed and then directional away from the bed toward the exit vents located low on the wall at the perimeter of the room. Although the unidirectional air is filtered, it is not considered sterile, and is not sterile over the operating room bed.

### **The Operating Room Procedures**

The goal is to provide for each surgical patient a safe clean environment. A surgical suite has specific equipment located within each room, related to the type of surgical procedure and specific patient population. Each room will have an operating room bed (surgical table), moveable overhead surgical lights, electrosurgical cautery device, laparoscopic camera, light boxes, if required, sequential compression sleeve device, forced air warming device, IV pumps, anesthesia machine, anesthesia cart, computer work station for the RN circulator, several stainless-steel tables of various sizes, suction device, and receptacles for trash, linen and sharps. As each piece of

equipment is put into use, it is then brought close to the surgical field. Many of the devices near the surgical field have their own internal motor and fan for cooling the motors.

Based on my education, training, knowledge, and many years of experience in the operating room environment as a nurse, it is my expert opinion that microorganisms, including bacteria, cannot be completely eliminated from the operating room environment. The equipment in the operating room, including equipment that will be close to the surgical field (e.g. anesthesia machine, electrosurgical cautery device, IV poles and pumps, anesthesia cart, computer monitors and hard drives, patient warming devices, suction bottles, overhead lights, compression sleeve device) contain bacteria and are not sterile. However, to decrease any potential contamination in the operating room, at the start of each day the horizontal surfaces of every piece of equipment is wiped with an EPA approved, hospital grade disinfectant. It is also my expert opinion that this action of wiping down equipment will decrease, not eliminate or kill all, the bacterial load on the surfaces of the equipment. Wiping the equipment also removes dust that has settled onto the surfaces when the room was unoccupied. After completion of this task, any additional equipment for the specific procedure is wiped down and brought into the room. For example, for a total hip arthroplasty, a specific positioning device may be used.

The sterile instruments and sterile drapes are brought into the operating room in a closed container identified as the items necessary for this patient and procedure. The team will assemble and check for all supplies prior to “opening” sterile supplies. During any procedure that will involve an implant, traffic into and out of that room is restricted. The prevailing practice in perioperative nursing is to gather extra supplies that might be needed to avoid leaving the room during the procedure. Additionally, the prevailing practice is the use of an extra staff member positioned outside the room to assist with communication needs or to retrieve extra needed supplies. This practice of extra supplies or an extra staff member is used in many operating rooms to decrease any additional traffic into the operating room. According to published literature, increased “door openings” causes more air current into the operating room and increases the risk to the patient of a potential for a surgical site infection.<sup>2 3</sup> Also according to the published literature, the air flow and currents in the operating room are disturbed by traffic and movement around the sterile field.

The surgical supplies are assembled then “opened” in specific locations in the operating room. As each item is opened, the package integrity and expiration date is checked for verification. The scrub nurse wears a hair covering, mask over the mouth, and then goes to the sink to complete her surgical scrub. The surgical scrub is either a timed event or done in an anatomical version. Either manner takes about three minutes to complete. The surgical scrub is to decrease the bacteria count on the hands of the surgical team, but it does not render the skin sterile. The scrub nurse then dons a sterile gown and gloves and begins the setup of the instrumentation for this procedure. She will check the sterile indicator inside each set of instruments to be assured of their sterility. The scrub nurse will position herself now away from the patient and any potential traffic involving patient care. Traffic in the room should be designated to facilitate movement of the patient, personnel, equipment, and supplies into and through the designated area. The scrub nurse will monitor and protect her sterile table from any accidental contamination. The sterile field should be prepared as

close as possible to the time of use. All items opened onto the sterile field should be opened according to the manufacturer's written instructions for use.<sup>4</sup>

### **The Patient Flow into the Operating Room**

The RN circulator will leave the operating room to meet the patient and begin her assessment of the patient. That assessment will include a review of the medical record. The RN circulator will then confer with the surgeon for any last minute or specific orders for this patient.

The surgical patient will then be brought into the operating room on a stretcher. The anesthesia provider (will have completed an assessment and consents prior to this moment) will accompany the patient and the RN. The patient moves from the stretcher to the operating room bed. Warm cotton blankets are placed on the patient at this time. Sequential compression stockings may be applied and turned on now. This device is used to decrease the risk of post-operative deep vein thrombosis (blood clot).

The anesthesia provider attaches monitoring lines and devices to the patient. After monitoring begins, the anesthesia provider administers the anesthesia for this patient. The patient is positioned for the procedure, and if necessary a tourniquet is applied to the correct limb. The forced air warming device replaces the cotton blankets on the patient. The Bair Hugger may be on an IV pole also used by anesthesia, or on a rolling cart. Both options make the Bair Hugger device easy to move and bring to the patient. The disposable Bair Hugger blanket is attached to the patient with an adhesive strip placed on the chest usually above the nipple line. The arms are covered with the disposable Bair Hugger blanket and secured with paper straps attached to the arm boards. The straps give easy access to the patient's IV line for the anesthesia provider. The Bair Hugger is then turned on to help the patient maintain a normal body temperature. The air directed through the Bair Hugger blanket to the patient is a gentle or mild air flow.

Research has shown forced-air warming devices to be safe for use in the operating room.<sup>5</sup> According to literature reviews conducted by others, the literature has not shown a correlation between post-operative surgical site infection and use of the forced-air warming device for patient warming.<sup>6 7</sup> Warming surgical patients has been the gold standard since the late 1990's. Cotton blankets, although cost effective, do not retain the heat needed to keep the patient at normothermia during the entire procedure. Warmed IV fluids and warmed irrigation solutions help decrease body heat loss but do not warm the patient.

The patient's skin is cleansed with an antiseptic solution to decrease the transient bacteria on the skin. The skin prep solutions must be used according to the manufacturer's recommendation to achieve the intended goal of decreasing bacteria. In my expert opinion, the skin is not sterilized by this process, but the skin preparation will render the skin as clean as possible. While the patient's skin is being prepared and prepped, the surgeon has gone to the scrub sink for surgical skin antisepsis. The surgeon's skin, like the scrub nurse, will be as clean as possible, not sterile, prior to donning the sterile gown and gloves. The surgeon will then don a sterile gown and gloves prior to placing any sterile surgical drapes onto the patient. The sterile drapes are placed in a sequence of steps to expose the prepped surgical site and to prepare a sterile work area for the

team. Usually the surgical site is squared off with four towels then a large sterile drape will cover that area. The larger sterile drape has a precut opening for the surgical site.

The sterile drape goes toward the head of the bed where the anesthesia provider will secure it while still allowing him access to the patient. The drape going toward the foot of the operating room bed will cover the entire patient and hang over the edge on both sides and end of the bed. Although it is a sterile drape, the area that is considered sterile is the top of the operating room bed only. The sterile gown worn by the team is considered sterile in the front from chest to the level of the sterile field, front of arms only. The cautery cord, suction tubing, and any drill cords will be carefully handed off from the sterile field to the RN Circulator. The RN circulator will attach the cords to their corresponding device. Sterile light handle covers may be attached to the surgical lights by any team member. Any pieces of equipment (instrument tables, mayo stands) that need to be within the surgical field where sterile instruments will be placed will be draped with a sterile drape.

The team present for a total joint procedure will consist of the surgeon, an assistant (MD, PA, RNFA, Surgical Resident), scrub nurse, RN circulator, technical support from the manufacturer (implant vendor), and anesthesia provider (MD or CRNA or both). Other staff may be present: cell saver technician or radiology technician if necessary.

A key component in sterile technique is the ability to recognize any break in technique and to correct the situation as soon as possible. Prior to the incision, a final time out will be conducted to verify: correct patient, correct site, site is marked, allergies, implants available, and other required information based on facility protocols.

After the time out, the scrub nurse brings her table of sterile instruments close to the patient and surgical site. The area immediately around the patient has traffic only of those in sterile attire (sterile gown and gloves). The RN circulator or other staff members maintain a distance of at least 12 inches away from the sterile field.

During the surgical procedure, the surgeon and the scrub nurse stand across the operating room bed from each other. Throughout the procedure, the surgical team is passing instruments and sponges back and forth across the surgical site which can potentially create air current disturbances.

Any extra supplies or implants required for a joint procedure are opened by the RN circulator and presented to the scrub nurse. Any implant opened is verified for size and description prior to opening the item.

Once the surgical procedure has concluded, a sterile dressing is placed on the surgical incision site. The drapes now considered contaminated are removed and placed in the appropriate container for disposal.

The patient is moved to a post-operative bed and taken to the PACU (recovery room). On arrival to PACU, the patient's vital signs are monitored. One of the important measurements is post-op temperature. If the temperature is below normal, the Bair Hugger may be used to continue to warm the patient.

The RN circulator returns to the operating room to assist the scrub nurse and ancillary staff in cleaning the room to prepare for the next surgical patient and procedure.

The Association of periOperative Registered Nurses (AORN) Guidelines recommend the use of forced air warming devices during surgical procedures for prevention of unintended hypothermia. AORN's recommendation is based on its review of the literature concerning forced air warming devices. In my many years of experience as a nurse in the operating room, the Bair Hugger device has been used on hundreds of surgical patients to assist with maintaining normal body temperature before, during, and after surgical procedures.

### **Conclusion**

In conclusion, it is my expert opinion that the operating room is a clean, but not completely sterile, environment. Bacteria cannot be completely eliminated from the operating room environment. The operating room equipment, including equipment that will be close to the surgical field (and not covered by sterile drapes) contain bacteria and are not sterile.

It is my expert opinion that many actions taken to reduce bacteria, e.g. patient's skin prep, wiping down equipment in the operating room, will not eliminate and kill all bacteria.

### **Material Considered**

The materials I have considered in reaching my opinions are the reference materials listed at the end of my report.

### **Prior Testimony**

I have not given expert testimony in the past four years.

### **Compensation**

My fees for this case preparation are as follows: \$225/hour for document review and \$350/hour for deposition with all travel fees covered.

Respectfully submitted,

*Antonia B Hughes RN BSN MA, CNOR*

Antonia Hughes, RN, BSN, MA, CNOR

References:

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<sup>1</sup> 2017 AORN Guideline for Safe Environment of Care, Part II.

<sup>2</sup> Andersson AE, Bergh I, Karlsson J, Eriksson BI, Nilsson K. Traffic flow in the operating room: an explorative and description study on air quality during orthopedic trauma implant surgery. *Am J Infect Contrtol*. 2012; 40(8) 750-755.

<sup>3</sup> Parah, P Stroh M, Casper DS, Parvizi J, Austin MS. Operating room traffic is a major concern during total joint arthroplasty. *Clin Orthop Relat Res*. 2012: 470 (10) 2690-2694.

<sup>4</sup> 2017 AORN Guideline for Sterile Technique, 2017.

<sup>5</sup> AORN Guideline for the Prevention of Unplanned Hypothermia 2017.

<sup>6</sup> Sikka KS, Prielipp, RC ; *J Bone Joint Sur Am* 2014 96 (24) Forced Air Warming Devices in Orthopedics: A Focused Review of the Literature.

<sup>7</sup> Kellam MD, Dieckmann LS, Austin PN. Forced-air warming devices and risk of surgical site infections. *AORN J*. 2013; 98 (4) 354-366.



**Antonia B. Hughes, MA, RN, CNOR**  
**11 Carvel Circle**  
**Edgewater, MD 21037**  
**(H) 410-224-4155**  
**(C) 410-991-0319**  
**Abhughes.rn@gmail.com**

### **Independent Perioperative Education Consultant**

Ms. Hughes has over thirty-five years of progressive Perioperative experience in clinical and administrative roles. The past ten years she has been focused on Perioperative Education.

- Successful development and facilitation of Periop 101 Course for new perioperative RNs with 100% pass rate
- Resource development for clinical and didactic educational programs, weekly for staff
- Patient Safety Initiatives program
- Perioperative personnel competency programs, self-assessment and skills review, annual skills day 200+ employees
- Program proposal development including implementation plan, required resources, cost /benefit analysis, and evaluation of effectiveness for each new department Internship
- Perioperative practice standards development for facility, wrote and developed guidelines
- Verbal and written communication within perioperative education arena, weekly written updates with all Interns regarding their practice progress
- Contact hour application completion for nursing and other perioperative organizations.
- Completion of renewal application for facility as provider of contact hour, via Maryland Nurses' Association
- Adjunct faculty for surgical technologist community college programs, successful clinical experiences for all students, 2 students each semester for 5+ years.
- Team preparation for Joint Commission Survey, successful survey no recommendations for the department
- Chair products standardization committee
  - Johns Hopkins Hospital and Johns Hopkins Bayview Medical Center

### **Experience**

- Perioperative Education Consultant to Lawrence General Hospital, Lawrence, MA 2016-2017
- Perioperative Education Consultant to Hackensack UMC Mountainside Hospital, Montclair, NJ 2015-2016
- Perioperative Education Specialist, Baltimore Washington Medical Center, Glen Burnie, MD 2007-2015
- Director Perioperative Services, Calvert Memorial Hospital, Prince Frederick, MD 2004-2007
- Manager, Operating Room, Johns Hopkins Bayview Medical Center, Baltimore, MD 2000-2004

## Awards

- **Jerry G. Peers Award** for Distinguished Volunteer Services to AORN
- **Leadership Award** Maryland Nurses Association District 3
- **Horizon Award** from Nursing School Alumni, Nebraska Methodist Hospital

## Education and Certifications

- Master of Arts in Management
  - College of Notre Dame of Maryland, Baltimore, Maryland
- Bachelor of Science in Nursing
  - College of Notre Dame of Maryland, Baltimore, Maryland
- Diploma in Nursing
  - Nebraska Methodist Hospital School of Nursing, Omaha, Nebraska
- Certified Nurse Operating Room (CNOR)
- Certified Epic Optime Trainer
- Team STEPPS facilitator, teacher and mentor; Maryland Hospital Association

## Publications and Presentations

- Developed competency statements perioperative practice for publication in national professional nursing organization materials
- AORN Guidelines presentations, local and national
- Articles in Nursing Spectrum and AORN Leadership Newsletter
- Chesapeake Bay Perioperative Consortium Poster at AORN National meeting
- Implementing AORN Recommended Practices for a Safe Environment of Care”, August 2013, Vol 98 No 2. AORN Journal
- Participated in Ornurserlink “Ask the Author” regarding “Implementing a Safe Environment of Care”.
- CNOR review course speaker
- Presenter at National and Chapter AORN meetings

## Professional Affiliations

AORN	Active member since 1980 National level activities: Transition into Practice Committee member 2016-2017, Chair 2017-2018 Recommended Practices Advisory Board, Chair 2009-2014 Syntegrity Committee member 2014-2015 Legislative Committee member and chair Patient Safety Task force member Presented to FDA regarding reprocessing single use devices consideration Nursing Practice committee member and chair
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Planning Committee member and Facilitator for Office of National Coordinator for Health Information and Technology, HHS seminar  
March 2014

Baltimore chapter activities include:

Secretary, President-elect, President, Board member  
Legislative Committee, Program committee chair, Nurse/vendor  
Night Celebration Committee Chair  
Scholarship Committee

Maryland Nurses  
Association

Legislative Committee chair  
Nurse's Night in Annapolis chair  
District 3 Secretary

Chesapeake Bay  
Perioperative  
Consortium

Founding member  
Member Curriculum committee and previous Chair

**Volunteer Activities**

Turnaround Women's Shelter fundraising event, annual activity,  
Relay for Life team member, annual event, planning committee,  
Sailing club leadership roles